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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

REXINA MIZE, an individual; MINH NGUYEN, an individual;

Plaintiffs,

v.

MENTOR WORLDWIDE, LLC; JOHNSON & JOHNSON; ETHICON, INC.; and DOES 1-100, inclusive,

Defendants.

Case No. 2:17-cv-01747-DMS-KS

Hon. Dolly M. Gee

DEFENDANTS MENTOR WORLDWIDE LLC, JOHNSON & JOHNSON AND ETHICON, INC.'S NOTICE OF MOTION AND MOTION TO DISMISS PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 12(b)(2) AND 12(b)(6); MEMORANDUM OF POINTS AND AUTHORITIES

[Filed concurrently with Request for Judicial Notice; Declaration of Mollie F. Benedict; and [Proposed] Order]

Date: May 5, 2017
Time: 9:30 A.M.
Courtroom: 8C

TO PLAINTIFFS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on May 5, 2017, at 9:30 a.m. or as soon thereafter as the matter may be heard in Courtroom 8C of the above-referenced court, located at 350 W. 1st Street, Los Angeles, California, 90012, Defendants Mentor Worldwide LLC ("Mentor"), Johnson & Johnson, and Ethicon, Inc. ("Ethicon") will and do hereby move to dismiss Plaintiffs' Complaint in its entirety, with prejudice, pursuant to Federal Rules of Civil Procedure 12(b)(2) and 12(b)(6).

This Motion is based on the grounds that the Court lacks personal jurisdiction over Johnson & Johnson and Ethicon. This motion is also based on the grounds that Plaintiff Rexina Mize's claims are expressly preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k because the device at issue in this action, a Mentor MemoryGel Silicone Breast Implant, is a Class III medical device that was evaluated and approved pursuant to the U.S. Food and Drug Administration's premarket approval (PMA) process. To the extent Plaintiff's claims seek to enforce federal regulations governing the device, they are also impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Further, Plaintiffs' claims are also inadequately pled and subject to dismissal for independent state law reasons. Because Plaintiff Rexina Mize's claims fail, Plaintiff Minh Nguyen's derivative loss-of-consortium claim fails.

This Motion is based upon this Notice of Motion and Motion; the attached Memorandum of Points and Authorities in support thereof; the concurrently filed Declaration of Mollie F. Benedict; the concurrently filed Request for Judicial Notice; the pleadings and documents on file in this case and on such other written or oral arguments as may be presented at or before the hearing on this Motion.

This motion is made following the conference of counsel pursuant to L.R. 7-3 which took place on March 30, 2017.

DATED: April 7, 2017

TUCKER ELLIS LLP

By: /s/Mollie F. Benedict
Mollie F. Benedict
Attorneys for Defendants

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

This is a product liability action concerning Mentor's MemoryGel Silicone Breast Implants, which are "Class III" medical devices approved by the U.S. Food and Drug Administration ("FDA") through the premarket approval process after the device's design, manufacture, and labeling was approved, and the product was found to be safe and effective by the FDA. Plaintiff Rexina Mize ("Plaintiff") asserts four claims against Mentor Worldwide LLC ("Mentor"), Johnson & Johnson, and Ethicon, Inc. ("Ethicon") (collectively, "Defendants") based on the manufacture and labeling of Mentor's MemoryGel Silicone Breast Implants. Plaintiff's spouse, Minh Nguyen, asserts a loss-of-consortium claim. The Court should dismiss Plaintiffs' claims against Johnson & Johnson and Ethicon under Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction and against all Defendants under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim on which relief can be granted.

First, the Court should dismiss all of Plaintiffs' claims against Johnson & Johnson and Ethicon for lack of personal jurisdiction. Johnson & Johnson and Ethicon are not subject to general jurisdiction because they are not incorporated in California, do not have their principal places of business here, and are not otherwise "at home" here. The Court also does not have specific jurisdiction over Johnson & Johnson and Ethicon because they engaged in no forum related activities related to the alleged injuries. Johnson & Johnson is a holding company and neither Johnson & Johnson nor Ethicon manufacture or sell Mentor MemoryGel Silicone Breast Implants.

Second, the U.S. Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), requires dismissal of Plaintiff Rexina Mize's ("Plaintiff") state-law claims (Counts 1–4). Plaintiff's claims, which challenge the product's safety and effectiveness, would impose manufacturing or labeling requirements different from, or in addition to, those approved by the FDA and therefore are preempted by the Medical

Device Amendments ("MDA"), 21 U.S.C. §§ 360 *et seq*., to the Federal Food, Drug and Cosmetic Act ("FDCA"). To the extent Plaintiff's claims seek to enforce federal regulations governing the device, they are also impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Plaintiff's attempt to circumvent express and implied preemption fails because there is no private right of action under the FDCA or the California FDCA. Plaintiff thus has not alleged a viable state-law "parallel" claim that survives express and implied preemption.

Third, Plaintiff Minh Ngyuen's loss-of-consortium claim (Count 5) fails on the ground that his claim is derivative of Plaintiff Rexina Mize's claims.

II. FACTUAL BACKGROUND

Plaintiff Rexina Mize was surgically implanted with Mentor MemoryGel Silicone Breast Implants. *See* Compl. ¶ 123. Plaintiff alleges that following her surgery, she experienced various injuries including chronic fatigue, muscle pain, joint pain, memory loss, and autoimmune issues. *Id*. ¶ 124. On January 3, 2017, she underwent explant surgery to remove her breast implants. *Id*. ¶ 128. Plaintiff filed her Complaint on February 2, 2017 asserting causes of action for: (1) negligence and negligence per se; (2) strict products liability – failure to warn; (3) strict products liability – manufacturing defect; (4) and implied warranty. Plaintiff's spouse, Minh Ngyuen, asserts a loss-of-consortium claim (Count 5). Plaintiff's factual allegations, and the basis for her damages, relate solely to the device's safety and effectiveness.

The Mentor MemoryGel Silicone Breast Implants implanted in Plaintiff are Class III medical devices as defined by 21 C.F.R. § 878.3530 and as such are subject to the most stringent controls under the MDA. *See Riegel*, 552 U.S. at 316. Because of its Class III status, the commercial sale of Mentor MemoryGel Silicone Breast Implants to healthcare professionals was conditioned upon the device receiving premarket approval from the FDA. *See* 21 C.F.R. § 878.3530(c). On December 12, 2003, Mentor submitted a PMA application for its MemoryGel Silicone Breast

Implants.[1] On November 17, 2006, the FDA found that the Mentor MemoryGel Silicone Breast Implants as designed, manufactured and labeled are safe and effective, and the FDA issued an Approval Order.[2] Thereafter, Mentor MemoryGel Silicone Breast Implants could only be sold to healthcare professionals in accordance with the design, manufacturing, and labeling specifications approved by the FDA. *Id.*; *see also* 21 C.F.R. § 801.109.

The Approval Order also outlined six post-approval studies which Mentor agreed to conduct as a condition of approval.[3] Contrary to Plaintiff's allegation that Mentor "fail[ed] to provide follow-through studies to the FDA" (Compl. ¶ 185), the FDA "[c]losely monitors the status and conduct of the on-going required post-approval studies so that data is collected, validated scientifically and disseminated widely." *See* FDA Update on the Safety of Silicone Gel-Filled Breast Implants, Executive Summary, attached as Exhibit 3 to RJN. The FDA also recognized that "[e]ach study had some patients who were not available for follow-up because they had died or discontinued participation." *Id*. at 9. Moreover, the FDA is empowered to withdraw premarket approval for a manufacturer's failure to comply with any post-approval requirements. *See* 21 C.F.R. § 814.82. The approvals for Mentor's MemoryGel Silicone Breast Implants, however, remain in effect and have never been suspended or withdrawn.

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[1] *See* November 17, 2006 PMA Approval Order and Summary of Safety and Effectiveness for P030053, (attached as Ex. 1 to Request for Judicial Notice ("RJN")).

[2] *Id.*; *see also* 72 Fed. Reg. 15,885, 15,886 (April 3, 2007) Notices, TABLE 1: List of Safety and Effectiveness Summaries for Approved PMAs Made Available from October 1, 2006 to December 31, 2006 (attached as Exhibit 2 to RJN).

[3] Each manufacturer of silicone gel-filled breast implants was required to complete the following post-approval studies as a condition of approval: (1) Core Post-Approval Study; (2) Large Post-Approval Study; (3) Device Failure Study; (4) focus group studies; (5) annual physician informed decision survey; and (6) adjunct study.

III. ARGUMENT

A. The Court Should Dismiss All Of Plaintiffs' Claims Against Johnson & Johnson and Ethicon For Lack Of Personal Jurisdiction

In California, a plaintiff bears the burden of making a prima facie showing that the court has general or specific personal jurisdiction over each defendant. *See, e.g.*, *Schwarzenegger v. Fred Martin Motor Co.*, 374 F.3d 797, 800 (9th Cir. 2004). "[M]ere 'bare bones' assertions of minimum contacts with the forum or legal conclusions unsupported by specific factual allegations will not satisfy a plaintiff's pleading burden." *Swartz v. KPMG LLP*, 476 F.3d 756, 766 (9th Cir. 2007) (citations omitted). As explained below, Plaintiffs cannot meet their burden. Thus, the Court should dismiss their claims against Johnson & Johnson and Ethicon.

1. *Plaintiffs cannot establish general jurisdiction.*

In *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), the U.S. Supreme Court held that general personal jurisdiction exists only where the defendant's "affiliations with the [forum] State are so 'continuous and systematic' as to render [it] essentially at home" there. *Id.* at 754 (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2851 (2011)). A corporation is deemed at "home" in the states where it is incorporated and has its principal place of business. *Id.* at 760. While general jurisdiction is not limited solely to these "paradigm" locations, a corporation will *not* be subject to general jurisdiction in a state merely because it "engages in a substantial, continuous, and systematic course of business" there. *Id.* at 760–61. Indeed, such a proposition is "unacceptably grasping." *Id.* at 761. Instead, a corporation may be subject to general jurisdiction outside the state where it is incorporated and has its principal place of business only in an "exceptional case." *Id.* at 761 n.19.

Here, Plaintiffs allege that Johnson & Johnson and Ethicon are incorporated and have their principal places of business in New Jersey. Compl. ¶¶ 20, 22. Accordingly, Johnson & Johnson and Ethicon are not subject to general jurisdiction in California. *See, e.g.*, *Ranza v. Nike, Inc.*, 793 F.3d 1059, 1069 (9th Cir. 2015) (finding no general

jurisdiction where defendant was not incorporated or had its principal place of business in forum); *Martinez v. Aero Caribbean*, 764 F.3d 1062, 1070 (9th Cir. 2014) (same); *Young v. Daimler AG*, 228 Cal. App. 4th 855, 867 (2014) (same); *Robinson v. Johnson & Johnson*, No. BC531848, 2015 WL 3923292, at *4 (Cal. Super. Ct. June 22, 2015) (same).

Moreover, this is not even close to an "exceptional case" within the meaning of *Daimler*. None of the allegations in the Complaint supports a finding that Johnson & Johnson or Ethicon have engaged in such "'continuous and systematic'" activity in California that they are "'comparable to a domestic enterprise'" of this state and therefore "'at home'" here. *Ranza*, 793 F.3d at 1069 (quoting *Daimler*, 134 S. Ct. at 758 n.11). To the extent Plaintiffs allege that Johnson & Johnson had "systematic and continuous contacts" in California (Compl. ¶ 30), that conclusory allegation is plainly insufficient to establish general jurisdiction. *See, e.g.*, *Daimler*, 134 S. Ct. at 760–63 (finding no general jurisdiction over parent corporation even after assuming that subsidiary was "at home" in California and that subsidiary's forum contacts were imputable to parent); *Robinson*, 2015 WL 3923292, at *4 (holding that it is "unquestionable" that Johnson & Johnson is not "at home" in California).

2. *Plaintiffs cannot establish specific jurisdiction.*

To establish specific jurisdiction, a plaintiff must demonstrate that (1) the defendant purposefully directed its activities at residents of the forum and (2) the litigation arises out of or relates to the defendant's forum-related activities. *See, e.g.*, *Schwarzenegger*, 374 F.3d at 802; *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014) ("For a State to exercise jurisdiction consistent with due process, the defendant's suit-related conduct must create a substantial connection with the forum State."); *see also Critical Care Diagnostics, Inc. v. Am. Ass'n Clinical Chem., Inc.*, No. 13CV1308 L(WMC), 2014 WL 842951, at *4 (S.D. Cal. Mar. 4, 2014).

As an initial matter, Plaintiffs' Complaint is littered with conclusory allegations directed to the collective "Defendants." *See, e.g.*, Compl. ¶¶ 1, 14, 28–34, 40–41. Conclusory and indiscriminate allegations such as these are insufficient to establish specific jurisdiction over Johnson & Johnson and Ethicon. *See, e.g.*, *Brazil v. Janssen Research & Dev. LLC*, --- F. Supp. 3d ---, 2016 WL 4844442, at *4 (N.D. Ga. Mar. 24, 2016) (dismissing Johnson & Johnson for lack of personal jurisdiction and explaining that allegations that "refer only to 'Defendants' . . . lack any specificity that could be used to sustain Plaintiff's initial burden of showing Defendant J&J's minimum contacts").[4]

In addition, Johnson & Johnson and Ethicon did *not* design, manufacture, or sell Mentor MemoryGel Silicone Breast Implants.[5] In fact, Plaintiffs specifically allege that at all relevant times, Mentor, *not* Johnson & Johnson or Ethicon, "designed, manufactured, tested, and distributed Mentor Breast Implants." Compl. ¶ 66. Public documents available on the FDA's website—which the Court may judicially notice—also confirm as much. For example, the Product Insert Data Sheet for Mentor MemoryGel Breast Implants shows that Mentor, *not* Johnson & Johnson, manufactures

[4] *See also Atuahene v. City of Hartford*, 10 F. App'x 33, 34 (2d Cir. May 31, 2001) ("By lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [plaintiff's] complaint failed to satisfy th[e] minimum standard [of fair notice]" in Federal Rule of Civil Procedure 8.); *Yost v. Nationstar Mortg. LLC*, No. 1:13–cv–00745–AWI–SAB, 2013 WL 4828590, at *3 (E.D. Cal. Sept. 9, 2013) ("A plaintiff suing multiple defendants must allege the basis of his claim against each defendant to satisfy Federal Rule of Civil Procedure 8(a)(2) . . . ."); *Corazon v. Aurora Loan Servs., LLC*, No. 11–00542 SC, 2011 WL 1740099, at *4 (N.D. Cal. May 5, 2011) ("By failing to differentiate among defendants or specify which defendant is the subject of Plaintiff's various allegations, Plaintiff's Complaint violates Rule 8(a)(2) because it fails to provide [defendant] with fair notice of its alleged misconduct.").

[5] *See* Johnson & Johnson 2015 Form 10-K, https://www.sec.gov/Archives/edgar/data/200406/000020040616000071/form10-k20160103.htm ("Johnson & Johnson is a holding company . . . .") (last visited Apr. 4, 2017).

and distributes the product.[6] Because Johnson & Johnson and Ethicon do not manufacture or sell Mentor MemoryGel Breast Implants, they did not purposefully direct any activities at residents of California and are therefore not subject to specific jurisdiction here. *See Brazil*, 2016 WL 4844442, at *7 (dismissing Johnson & Johnson for lack of personal jurisdiction in part because it is a holding company, "Plaintiff has not contested Defendants' evidence showing that Defendant J&J is not the manufacturer of [the product] and instead is a holding company."); *see also Androphy v. Smith & Nephew Inc.*, 31 F. Supp. 2d 620, 622 (N.D. Ill. 1998) (finding that Johnson & Johnson is not subject to personal jurisdiction because "[i]t is a holding company which neither transacts business nor contracts to provide products or services in Illinois"); *Robinson*, 2015 WL 3923292, at *4 (dismissing Johnson & Johnson from product liability case based on lack of personal jurisdiction and finding that it "is a holding company which does not itself operate the design, manufacturing and sales operations which form the commercial heart of its business" and that "those businesses are conducted by various subsidiary corporate entities"). This Court should follow these well-reasoned authorities. *See also Holland Am. Line Inc. v. Wärtsilä N. Am., Inc.*, 485 F.3d 450, 459 (9th Cir. 2007) (affirming dismissal of holding company for lack of personal jurisdiction because it "has not put *any* products into the stream of commerce").

Moreover, Plaintiffs have not alleged any facts that would support the imputation of Mentor's California contacts to Johnson & Johnson and Ethicon for purposes of specific jurisdiction. While Johnson & Johnson is the parent of Mentor and Ethicon is Mentor's sole member, "[t]he existence of a parent-subsidiary relationship is insufficient, on its own, to justify imputing one entity's contact with a forum state to another for the purpose of establishing personal jurisdiction." *Ranza*, 793 F.3d at 1070;

[6] *See* https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM245623.pdf (last visited Apr. 7, 2017), Ex. 4 to RJN.

see also Holland, 485 F.3d at 459; *Lisa McConnell, Inc. v. Idearc, Inc.*, No. 09–CV–00061–IEG (AJB), 2010 WL 364172, at *7 (S.D. Cal. Jan. 22, 2010).[7]

B. Legal Standard

Dismissal is warranted under Rule 12(b)(6) when a plaintiff fails to allege facts sufficient "to raise a right to relief above the speculative level" or fails to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56, 570 (2007). This "plausibility" standard applies to all claims brought in federal court. *See Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009). A claim is plausible only if the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678. Where a complaint pleads facts that are "merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (internal quotation marks omitted). While a court generally must accept well-pleaded facts as true, this

[7] To support imputation of Mentor's California contacts to Johnson & Johnson or Ethicon on an alter-ego or agency theory, Plaintiffs at a minimum would need to allege facts showing that Johnson & Johnson and Ethicon exercised sufficient control over Mentor. *See, e.g.*, *Los Gatos Mercantile, Inc. v. E.I. DuPont de Nemours & Co.*, No. 13–cv–01180–BLF, 2015 WL 4755335, at *4 (N.D. Cal. Aug. 11, 2015) (holding that allegations that parent "exerted considerable control over the activities and operations" of subsidiary and controlled its "marketing, purchasing, pricing, management and/or operating policies" were insufficient to impute subsidiary's contacts to parent on alter-ego or agency theory). But Plaintiffs have alleged *no* such facts. *See generally* Compl. Accordingly, there is no basis to impute Mentor's alleged forum contacts to Johnson & Johnson and Ethicon for purposes of specific jurisdiction. *See, e.g.*, *Brazil*, 2016 WL 4844442, at *5 (holding that plaintiff did not make sufficient showing to impute contacts of subsidiaries to Johnson & Johnson because "[t]here is no evidence in the record and no factual allegations in the Complaint even suggesting" that Johnson & Johnson exercised sufficient control over these defendants); *Androphy*, 31 F. Supp. 2d at 622 (finding no specific jurisdiction over Johnson & Johnson based on Illinois contacts of "separate" subsidiary); *see also Mack v. AmerisourceBergen Drug Corp.*, No. RDB–08–688, 2009 WL 4342513, at *8 (D. Md. Nov. 24, 2009) (dismissing Johnson & Johnson because "Plaintiffs have provided no justification for disregarding the parent/subsidiary distinction").

principle does *not* apply to legal conclusions, conclusory allegations, or unwarranted factual inferences. *See id.* ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."); *Twombly*, 550 U.S. at 555 ("[P]laintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.")

A court also need not accept as true allegations contradicted by judicially noticeable facts. *Shwarz v. United States*, 234 F.3d 428, 435 (9th Cir. 2000). Reference to public FDA records that are entitled to judicial notice does not necessitate conversion of a motion for judgment on the pleadings to one for summary judgment.[8] *See Shaw v. Hahn*, 56 F.3d 1128, 1129 n.1 (9th Cir. 1995) (noting that a "court may look beyond the plaintiff's complaint to matters of public records" without converting the Rule 12(b)(6) motion into one for summary judgment) (citations omitted).

C. Federal Law Bars Plaintiff's Claims

1. The MDA Preempts Additional or Different State Law Requirements Related to the Safety or Effectiveness of a Federally Approved Medical Device

The Supremacy Clause of the United States Constitution states that the "Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const., art. VI, cl. 2. Because federal law is supreme, any "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992).

[8] Because PMA approvals are documented in the Federal Register, courts are *required* to take judicial notice of them. *See* 21 C.F.R. § 814.44(d)(1) (2010) ("FDA will publish in the Federal Register after each quarter a list of the approvals announced in that quarter."); 44 U.S.C. § 1507 ("[t]he contents of the Federal Register shall be judicially noticed."). It is a matter of public record that Mentor MemoryGel Silicone Breast Implants first received PMA on November 17, 2006. *See* Exhibits 1 & 2 to RJN.

(a) Medical Device Amendments of 1976

Congress gave the FDA exclusive regulatory authority over medical devices when it amended the Food, Drug and Cosmetic Act by enacting the Medical Device Amendments of 1976 ("MDA"). 21 U.S.C. §§ 301 *et seq*. By establishing a regulatory regime for the oversight of medical devices, the amendments were expected "to provide for the safety and effectiveness of medical devices intended for human use." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996) (citing the preamble to the MDA, 90 Stat. 539) (internal quotations omitted).

The MDA establishes three classes of medical devices based on the level of oversight required to ensure their safety. *Riegel*, 552 U.S. at 316; 21 U.S.C. § 360c(a)(1). Of the three classes, a Class III device receives the most federal oversight, and requires premarket approval by the FDA. *Id*. Generally, a device receives a Class III assignment if it cannot be established that a less stringent classification would "provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)). Premarket approval of a Class III device is a "rigorous process" requiring an applicant to submit "full reports of all studies and investigations relating to the device's safety or effectiveness; a 'full statement of the components, ingredients, and properties . . . '; a full description of the manufacturing methods and the facilities and controls used for the device's manufacturing; [and] examples of the proposed labeling." *Id.* at 317–18.

The FDA spends an "average of 1,200 hours" on each premarket approval application. *Id.* (quoting *Lohr*, 518 U.S. at 477). In determining whether to grant premarket approval of a Class III device, the FDA must, among other things, "weigh[] any probable benefit to health from the use of [a] device against any probable risk of

injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). The FDA will also "rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of [the device's] safety and effectiveness." 21 U.S.C. § 360e(d)(1)(A). The FDA may condition its grant of premarket approval upon certain requirements. 21 U.S.C. §§ 360e(d), 360j(e)(1). Once premarket approval has been granted, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Moreover, approved devices are also subject to ongoing reporting requirements related to the device's health and safety. *Id.* A manufacturer must inform the FDA of studies and investigations of its devices, as well as incidents where the device caused or could have caused serious injury and the FDA retains the authority to withdraw approval based on this information. *Id.*

Importantly, to ensure FDA oversight is not controverted by state regulatory measures, the MDA contains an express preemption provision which states that: "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—[¶] (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and [¶] (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

(b) Medical Device Preemption Under *Riegel*

In *Riegel*, the United States Supreme Court considered whether the MDA's preemption provision barred common law claims that challenged the safety and effectiveness of Class III medical devices which received approval through the PMA process. 552 U.S. at 320. At issue was a premarket approved Class II catheter marketed by Medtronic. *Id*. The plaintiffs alleged the catheter was "designed, labeled, and manufactured in a manner that violated" state common law, and that these defects

caused severe injuries and asserted claims for "strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter." *Id*.

The *Riegel* court unequivocally construed the MDA's express preemption provision to preempt the plaintiffs' state law claims against the PMA-approved catheter. In so doing, the court established a two-step inquiry for determining whether state law claims are preempted by the MDA. First, the court "must determine whether the Federal Government has established requirements applicable to" the medical device at issue. *Id.* at 321. Second, if there are applicable federal requirements, the court must then determine whether the "common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id*. at 322.

As to the first part of the inquiry, *Riegel* held that the FDA's premarket approval imposes federal requirements because it is granted "only after [the FDA] determines that a device offers a reasonable assurance of safety and effectiveness" and because "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application." *Id*. at 323. In reaching this conclusion, the *Riegel* court expressly distinguished its prior holding in *Lohr*, 518 U.S. at 470, where the court had held that substantial-equivalence review pursuant to 21 U.S.C. § 510(k) did not impose a device-specific federal "requirement." *Riegel*, 552 U.S. at 322. Given that substantial-equivalence review enables medical devices to be "marketed only so long as they remain substantial equivalents of the relevant pre-1976 devices," the court regarded the process as an exemption rather than a requirement. *Id*.; *Lohr*, at 493–94.

Riegel is consistent with federal authority construing the PMA process to impose a federal requirement for the purpose of preemption. *See Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085, 1091 (C.D. Cal. 2011) (recognizing that there is "no

dispute" that federal requirements apply to the device at issue approved through the PMA process); *Walker v. Medtronic, Inc.*, 670 F.3d 569, 577 (4th Cir. 2011) ("[B]ecause [] Class III devices are required to undergo the premarket approval process, federal requirements exists with respect to [] Class III devices.").

As to the second part of the preemption inquiry, *Riegel* found that common law tort duties impose "'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Riegel*, 552 U.S. at 323–24. The Court reasoned that common law liability implies that the defendant had a legal duty and that "a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Id*. at 324. Rejecting the notion that a state-law "requirement" was limited to a state statute or regulation, the *Riegel* court reasoned that "[s]tate tort law that requires a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Rhynes v. Stryker Corp.*, No. 10–5619 SC, 2011 WL 5117168, at *4 (N.D. Cal. Oct. 27, 2011) (quoting *Riegel*, 522 U.S. at 325); *see also Nimtz v. Cepin*, No. 08cv1294 L(AJB), 2011 WL 831182, at *4 (S.D. Cal. Mar. 3, 2011) ("[S]tates are not permitted to indirectly regulate the safety and effectiveness of an FDA approved medical device through the tort system."); *Grant v. Corin*, No. 3:15–CV–169–CAB–BLM, 2016 WL 4447523, at *3 (S.D. Cal. Jan. 16, 2016) (concluding "California 'requirements' include common law duties").

In *Riegel*, the U.S. Supreme Court concluded that both elements of its two–step inquiry were satisfied. Approval of a Class III medical device through the PMA process necessarily established "federal requirements." *Riegel*, 552 U.S. at 321–23. Further, "reference to a State's 'requirements' includes its common-law duties." *Id*. at 324. Plaintiffs' state tort law claims against the PMA-approved catheter were thus held to be preempted by the express preemption provision of the MDA. *Id*.

Following *Riegel*, "courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence . . . to breach of warranty . . . to failure to warn and manufacturing-and-design-defect claims. . . to negligence per se." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig. ("Medtronic Leads")*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (collecting cases). Likewise, California courts and the Ninth Circuit routinely apply § 360k(a) to dismiss cases against PMA-approved Class III medical devices based on preemption. *See Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK(AJWx), 2014 WL 3056026 (C.D. Cal. June 25, 2014) (dismissing strict liability and design defect claims as expressly preempted).[9]

(c) Implied preemption under *Buckman*

Riegel established that a state claim may *only* proceed if it "provid[es] a damages remedy for claims premised on a violation of FDA regulations" if "the state duties in

[9] *See also Anderson v. Medtronic*, No. 14–cv–00615–BAS(RBB), 2015 WL 2115342 (S.D. Cal. May 6, 2015) (dismissing strict liability, negligence, and negligence per se claims as expressly preempted); *Kashani-Matts v. Medtronic*, No. SACV 13–01161–CJC(RNBx), 2013 WL 6147032 (C.D. Cal. Nov. 22, 2013) (granting motion to dismiss all plaintiff's claims as preempted); *Simmons v. Boston Sci. Corp*., No. CV 12–7962 PA (FFMx), 2013 WL 1207421 (C.D. Cal. Mar. 25, 2013) (dismissing strict liability manufacturing, design and failure to warn claims dismissed as preempted); *Erickson*, 2011 WL 7036060 (granting judgment on the pleadings against all claims involving several pacemakers approved through PMA and PMA-equivalent processes); *Rhynes*, 2011 WL 5117168 (granting motion to dismiss as to all claims involving hip implant based on preemption); *Norton v. Indep. Tech., LLC*, No. 2:10–cv–03218–MCE–JFM, 2011 WL 3584491 (granting motion for judgment on the pleadings on preemption grounds against all claims in case involving PMA motorized stair-climbing wheelchair); *Nimtz*, 2011 WL 831182 (granting motion to dismiss on preemption grounds against all claims involving pacemaker approved via PMA); *Cohen v. Guidant Corp.*, No. CV–05–8070–R, 2011 WL 637472 (C.D. Cal. Feb. 15, 2011) (granting motion to dismiss on preemption grounds for pacemaker approved through PMA-equivalent process); *McGuan v. Endovascular Techs., Inc.*, 182 Cal. App. 4th 974 (2010) (holding MDA preempted strict product liability, negligence, breach of express and implied warranties, and consumer protection claims).

such a case parallel, rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (internal citations and quotations omitted). However, claims premised *solely* on a violation of MDA requirements are impliedly preempted under *Buckman*. 531 U.S. at 352–53. A "parallel" state claim must "[rely] on traditional state tort law which has predated the federal enactments in question." *Id.* at 353. There is thus a "'narrow gap' through which a state-law claim must fit to escape preemption by the FDCA: 'The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).'" *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (quoting *In re Medtronic, Inc., Sprint Fidelis Prods. Liab. Litig.,* 623 F.3d 1200, 1204 (8th Cir. 2010)) (emphasis in both).

The FDA holds the exclusive authority to enforce the regulations and levy penalties if it finds that a manufacturer has committed a violation; indeed, "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). As such, a private litigant cannot sue a defendant for allegedly violating the FDCA. *See Buckman*, 531 U.S. at 349 n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions . . . ."); *see also Perez*, 711 F.3d at 1119 (finding plaintiffs fraud claim preempted because it "exist[s] solely by virtue of the FDCA . . . requirements") (citations omitted). "Claims not tied to state law tort duties are essentially private actions to enforce the FDCA and are barred by [21 U.S.C. § 337(a)]." *Hawkins v. Medtronic, Inc.*, No. 1:13–CV–00499 AWI SKO, 2014 WL 346622, at *4 (E.D. Cal. Jan. 30, 2014). Moreover, claims may be subject to implied preemption if they "seek to enforce an exclusively federal requirement not grounded in traditional state tort law." *Kashani-Matts*, 2014 WL 819392, at *2 (citing *Buckman*, 531 U.S. at 352–53).

2. The FDA Has Mandated Specific Requirements for the Manufacture, Design, and Labeling of Breast Implants

The first step of the preemption inquiry is the determination as to "whether the Federal Government has established requirements applicable to" the medical device at issue—*i.e.*, to Mentor MemoryGel Silicone Breast Implants. *Riegel*, 552 U.S. at 321. The Mentor MemoryGel Silicone Breast Implant at issue in this case is a Class III device approved by the FDA through the PMA process. *See* Ex. 1 to RJN, FDA PMA Approval Order. The Mentor MemoryGel Silicone Breast Implants at issue has been manufactured and marketed pursuant to a valid and current PMA, and such approval has never been revoked, suspended, or withdrawn. *See Riegel*, 552 U.S. at 319–20 ("The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling.").

The FDA approved specifications relative to the design, manufacture and labeling of the Mentor breast implants at issue are the only standard of care applicable thereto. *Id.* at 325. Therefore, any state-law products liability claims attempting to impose design, manufacture, or labeling requirements different from, or in addition to, those approved as safe and effective by the FDA are preempted by the MDA, 21 U.S.C. §§ 360 *et seq*., to the FDCA, 21 U.S.C. §§ 301 *et seq*.

3. Plaintiff's State Law Claims (Counts 1–4) Conflict with the FDA Requirements for the Manufacture, Labeling, and Alteration of the Breast Implants and Are Preempted

The second step of the preemption inquiry is the determination of whether Plaintiff's state law claims rely on any requirement of California law applicable to Mentor MemoryGel Silicone Breast Implants "that is 'different from, or in addition to' federal requirements and that 'relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.'" *Riegel*, 552 U.S. at 323 (quoting 21 U.S.C. § 360k(a)). The MDA expressly preempts any state law claim that would impose different or additional duties relating to any requirement

imposed through the PMA process. *Id*. at 327–28; *Erickson*, 2011 WL 7036060, at *4. Like the plaintiffs in *Riegel*, by alleging state law tort claims, Plaintiff is, in effect, attempting to impose manufacturing and warning requirements upon the Mentor MemoryGel Silicone Breast Implant which conflict with, or add a greater burden to, the specific federal requirements imposed by the FDA through premarket approval.

Plaintiff's threadbare and conclusory claims against Mentor for negligence and negligence per se (Count 1), strict liability failure to warn (Count 2), strict liability manufacturing defect (Count 3), and breach of implied warranty (Count 4) challenge the safety and effectiveness of the PMA-approved Mentor MemoryGel Silicone Breast Implants. *See* Compl. ¶¶ 131–241.

The first cause of action, which asserts negligence and negligence per se is preempted under *Riegel*. Plaintiff asserts that Defendants breached their duty by failing to "warn Plaintiffs and their physicians by not reporting the risk of serious defect the Defendants knew or should have known. . . ." Compl. ¶ 135. Plaintiff does not allege that the labeling of her Breast Implants deviated from the FDA-approved labeling. She nonetheless impermissibly seeks to impose labeling requirements that go beyond what federal law requires. *See Riegel*, 552 U.S. at 327–28.

The second cause of action, which asserts strict liability failure to warn, is also preempted under *Riegel*. In support of her claim, Plaintiff makes the conclusory allegation that the MemoryGel Silicone Breast Implants were "defective and unreasonably dangerous . . . in that they contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and complications associated with the [product] . . . ."[10] Compl. ¶ 183. Again, Plaintiff does not allege that the labeling of her MemoryGel Silicone Breast Implant deviated from the FDA-approved

[10] Plaintiff *cannot* premise her claim on a failure to warn her directly about that purported risk. *See* Compl. ¶ 181. Under the learned intermediary doctrine, a medical device manufacturer's duty is to warn the prescribing physician, *not* the patient. *See, e.g.*, *Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004).

labeling but nonetheless seeks to impose labeling requirements that go beyond federal law. *See Riegel*, 552 U.S. at 327–28; *Houston v. Medtronic*, 957 F. Supp. 2d 1166, 1177 (C.D. Cal. 2013) ("Plaintiff aims to foist upon Defendants labeling or warning requirements 'in addition to' what federal law requires. Therefore, the claim is expressly preempted.").

In the third cause of action for strict liability manufacturing defect, Plaintiff maintains that her implants "were defective in their manufacture due to not meeting the current good manufacturing practices required by the FDA." Compl. ¶ 218. Plaintiff does not allege that Defendants deviated from any *specific* manufacturing requirement imposed by the FDA through the PMA process, but instead relies on allegations that Defendants purportedly violated vague and generic Current Good Manufacturing Practices ("cGMPs"). *See id.* ¶ 221. As explained in Part III.C.4.a, such assertions are unacceptably vague and insufficient to survive express preemption.

The fourth cause of action for breach of implied warranty asserts that the implants were "not reasonably safe for its expected purpose, nor reasonably fit for the ordinary purpose for which it was sold and/or used and it did not meet expectations for the performance of the product." Compl. ¶ 234. Such boilerplate breach of warranty claims are not only inadequately pled, but are also routinely dismissed as expressly preempted. *See De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1097 (N.D. Cal. 2016) (dismissing breach of implied warranty claim as preempted because a determination of whether the product lacks the most basic degree of fitness for ordinary use would bear directly on its FDA-approved safety and effectiveness).

The reasoning behind dismissal of each of Plaintiff's claims is in line with *Riegel* and its progeny. Each claim would require "judges and juries to second-guess the balancing of benefits and risk of a specific device to their intended patient population—the central role of the FDA. . .." *Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004) (quoting the FDA's Amicus Curiae Letter Brief at 25–26). *Riegel*

explicitly held that state law tort claims, including causes of action for strict liability, negligence, and breach of implied warranty, impose requirements that are different from, or in addition to, the device-specific federal requirements, and are thus preempted. *Riegel*, 552 U.S. at 324.

The same reasoning applies here. Plaintiff's strict liability, negligence, and warranty claims are devoid of any plausible allegations that the premarket-approved Mentor breast implants at issue in this case were not manufactured and labeled in accordance with the specifications approved by the FDA through the PMA process. By contending that the Mentor breast implants were, nevertheless, defective, Plaintiff seeks to impose requirements regarding the manufacture, marketing or labeling of the Mentor breast implants that are different from, or in addition to, what the FDA approved. Plaintiff has therefore failed to allege facts sufficient "to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 547. Consequently, Plaintiff's negligence (Count 1), strict liability claims (Counts 2 & 3), and breach of implied warranty (Count 4) claims fall squarely within the MDA's express preemption provision and in accordance with *Riegel* and its progeny, Plaintiff's claims should be dismissed.

4. Plaintiff Has Not Pled a Plausible Parallel Claim That Survives Express and Implied Preemption.

Even if Plaintiff's strict liability, negligence, and implied warranty claims escape express preemption—which they do not—they still fail to assert a viable parallel claim. In addition, Plaintiff's failure to warn and negligence per se claims are impliedly preempted as an impermissible attempt to enforce federal regulations. As noted above, "express preemption and implied preemption leave only a 'narrow gap' through which the plaintiff's claims must fit in order to survive." *Perez*, 711 F.3d at 1120. Moreover, a plaintiff "cannot simply incant the magic words '[defendant] violated FDA regulations' in order to avoid preemption." *Simmons*, 2013 WL 1207421, at *4.

(a) Plaintiff fails to plead a parallel manufacturing defect claim

Plaintiff's manufacturing defect claim, which relies on vague and unspecified cGMPs, does not support a parallel claim that survives express preemption. "CGMPs are guidelines that do not create a federal requirement, and a claim based on alleged failure to comply with the guidelines fails to plead violation of a federal requirement." *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 198 (E.D.N.Y. 2015). A claim mandating "compliance with such 'vague' standards effectively imposes "different, or additional" requirements, and is preempted by § 306." *McPhee v. DePuy Orthopedics, Inc.*, No 3:11-287, 2013 WL 5462762, at *6–7 (W.D. Pa. Sept. 30, 2013) ; *Medtronic Leads*, 592 F. Supp. 2d at 1157–58. (noting that, since CGMPs are "simply too generic, standing alone, to serve as the basis for Plaintiff's manufacturing-defect claim[,]" to hold Medtronic liable for conduct, in "the absence of a specific requirement in the CGMPs. . . would impose requirements 'different from, or in addition to' those under federal law" (citations omitted)).

(b) Plaintiff's alleged regulatory violations do not support a parallel claim

Plaintiff recites several alleged "violations of federal regulations" in an attempt to plead a parallel claim. Each alleged "violation" however, is insufficient to establish a claim that escapes express and implied preemption.

(i) Form 483s

Plaintiff's citation to FDA Form 483s cannot serve as the predicate for a parallel claim. First, five of the six alleged "violations of federal law" occurred *before* the 2006 approval of the Mentor MemoryGel Breast Implants and thus could not be remotely related to Plaintiff's implants. Second, Plaintiff does not link any alleged violations to her claims. To escape implied preemption, Plaintiff "must allege that the irregularities documented in the 483s resulted in a manufacturing defect that caused her injuries." *De La Paz*, 159 F. Supp. 3d at 1094; *see also Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1283 (N.D. Ga. 2014) (finding that

"[p]lainitff lists a number of critical observations, but fails to allege how they are linked to her claims."). Here, Plaintiff has failed to satisfy her basic pleading obligations and these allegations do nothing to establish that Mentor violated any specific manufacturing specification that caused her alleged injuries.[11]

(ii) Changes Being Effected

Plaintiff alleges that Mentor violated federal requirements by failing to unilaterally file a "Special PMA Supplement—Changes Being Effected" ("CBE") Compl. ¶ 61 However, CBE labeling pursuant to 21 C.F.R. § 814.39 is permissive, and thus cannot serve as the basis for a parallel claim. Medical device manufacturers are not required to update the labeling of their product. 21 C.F.R. § 814.39(d) permits, but does not require, interim supplemental warnings. Thus, any state law claim purporting to require an interim supplemental warning is preempted because it is "in addition to" the federal requirement. *See Houston*, 957 F. Supp. 2d at 1178 (citing *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) (Watford J., concurring) (finding plaintiff's failure to warn claim expressly preempted because FDA "regulations *permit* Defendants to issue such post-sale warnings, those regulations do not require such warnings"); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 783 (D. Minn. 2009) (finding that a failure to warn claim cannot parallel § 814.39(d) because that section merely *permits* a device manufacturer to make a temporary change to the label, whereas a successful failure-to-warn claim would *require* such a claim).

(iii) Adverse Event Reporting

[11] Plaintiff also alleges that Mentor somehow violated the conditions of the PMA because "no PMA supplement notifying the FDA of Mentor's acquisition" was filed. Compl. ¶¶ 100–101. First, the PMA for Mentor's MemoryGel Breast Implants was filed by Mentor and the Mentor continues to hold the PMA. *See* Ex. 5 to RJN. This federal regulation governing a change of PMA ownership is thus wholly inapplicable. Second, Plaintiff does not allege—nor could she ever plausibly allege—that any failure to notify the FDA of a change in ownership is causally related to her injuries.

Plaintiff also makes the unsupported allegation that Mentor failed to report adverse events in violation of federal requirements. Plaintiff neither alleges any actual adverse event that Mentor did not report, nor does she explain how any purported failure to report unspecified adverse events caused her injury. "To survive a motion to dismiss on a state law failure to warn claim that is parallel to federal regulations the complaint 'must include allegations of actual adverse events that Defendants did not report.'" *Weaver v. Ethicon*, No. 16cv257–GPC (BGS), 2016 WL 7098781, at *6 (S.D. Cal. Dec. 6, 2016) (citing *Grant*, 2016 WL 4447523, at *7). This claim lacks any factual support, is insufficient under *Twombly/Iqbal* and cannot form the basis of a parallel claim.

(c) Plaintiff's failure to warn and negligence per se claims are impliedly preempted.

Additionally, Plaintiff has not pled a valid parallel failure to warn or negligence per se claim because her claim is predicated exclusively on Mentor's alleged violation of federal requirements pursuant to the FDCA. Courts in California have held that a cause of action for negligence per se based on a violation of the FDCA exists "because of federal law and [is] therefore preempted." *Anderson*, 2015 WL 2115342, at *8–9 (finding negligence per se action premised on violation of applicable federal statutes and regulations relating to medical devices was impliedly preempted under *Buckman* because they existed "because of federal law"); *Grant*, 2016 WL 444752, at *4 dismissing negligence per se claim as impliedly preempted because the statutes forming the claim were FDA-imposed regulations); *Dunbar*, 2014 WL 3056026, at *5–6 (dismissing negligence per se claim as impliedly preempted under *Buckman*).

As part of the basis for her negligence per se claim, Plaintiff alleges that Mentor breached "regulations and testing requirements imposed by the granting of the PMA by the FDA for MemoryGel Silicone Gel Breast Implants, including the requirement that follow-through studies be conducted." Compl. ¶ 172. However, Plaintiff fails to point to any *state-law claim* that parallels those alleged federal requirements. *See Wolicki-*

Gables v. Arrow Intern., Inc., 634 F.3d 1296,1300 (11th Cir. 2011)) (to state a parallel claim that avoids preemption, a claim must be based on a state law duty that is "genuinely equivalent" to the federal requirement). In fact, there is no state-law claim requirement that a manufacturer conduct "follow-through studies." The adjudication of Plaintiff's claims thus relies solely on the existence of federal requirements and is impliedly preempted. Plaintiff may not supplant the exclusive enforcement authority of the FDA by suing for alleged violations of the FDCA. Her negligence per se claim and strict liability failure to warn claim are therefore impliedly preempted and should be dismissed.[12]

Plaintiff's attempted reliance on California's Sherman Law as a parallel state law claim is also misplaced. Like the FDCA, the Sherman Law does not provide for a right of private enforcement. *Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc.*, 922 F. Supp. 299, 317 (C.D. Cal. 1996)); *see also Grant*, 2016 WL 4447523, at *2–3 (dismissing Sherman Law claim because it does not permit a private right of action).[13]

5. Plaintiff Has Not Alleged A Causal Nexus Between the Alleged Violations and Her Injuries.

Plaintiff's attempted parallel claim also fails because she has not plausibly alleged that any violations of federal requirements caused her specific injury. To properly plead parallel claims that survive preemption, a plaintiff must allege (1) the violation of a specific federal requirement applicable to the device; (2) the violation of an identical state-law duty; and (3) that the predicate federal violation caused his or her injuries." *Millman v. Medtronic*, No. 14–cv–1465, 2015 WL 778779, at *4 n.2 (D.N.J. Feb. 24, 2015).

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[12] To the extent Plaintiff's strict liability failure-to-warn claim (Count 2) is based on similar alleged violations of the FDCA, that claim is impliedly preempted as well.

[13] To the extent Plaintiff asserts that her Implants were "adulterated" or "misbranded," (Compl. ¶¶ 54, 60) such claims are also impliedly preempted under *Buckman*. *See Frere*, 2016 WL 1533524, at *7.

Here, Plaintiff fails to draw the necessary causal link between the alleged federal violations and her injuries. Plaintiff has alleged no facts suggesting how the progress of Mentor's post-approval studies caused her injuries; "she merely alleges the conclusion of causation itself." *Frere v. Medtronic*, No. EDCV 15–02338–BRO (DTBx), 2016 WL 1533524, at *6 (C.D. Cal. Apr. 6, 2016). She makes the speculative and unsupported assertion that "of the patients who were accounted for, significant numbers reported systemic ailments *which can only be attributed to gel bleed*." Compl. ¶ 92 (emphasis added). She has articulated no facts, however, to support her bald conclusion that additional information from patients in post-approval studies would reveal an issue with "gel bleed" or would result in the FDA requiring different labeling. Further, as Plaintiff herself highlights by referencing the FDA's website regarding Mentor's post-approval studies, the FDA is already aware of the status of each post-approval study, but has not required Mentor to take any action or alter the warnings already in place.

6. Numerous Courts Have Held State Law Claims Related to Breast Implants Are Preempted

Numerous courts – both before and after *Riegel* – have for years held that state law claims related to PMA-approved breast implants are preempted. *See*, *e.g.*, *Malonzo v. Mentor Worldwide, LLC*, No. C 14–01144 JSW, 2014 WL 2212235 (N.D. Cal. May 28, 2014) (dismissing product liability claims against Mentor regarding saline breast implants as expressly preempted); *Ford v. Mentor Worldwide, LLC,* No. 2:13-cv-06317 (E.D. La. Dec. 17, 2013) (granting Mentor's motion to dismiss all of plaintiff's product liability claims regarding saline breast implants as preempted under *Riegel*) (order attached as Exhibit A to Benedict Decl. ¶ 3); *Harris v. Mentor Worldwide LLC*, No. 12-cv-916 (E.D. Cal. Aug. 21, 2012) (following *Riegel* and dismissing plaintiff's product liability claims regarding saline breast implants against Mentor as preempted) (minute order attached as Exhibit B to Benedict Decl. ¶ 4); *Couvillier v. Allergan Inc.*, No. 10–1383, 2011 WL 8879258, at *1–2 (W.D. La. Jan.

20, 2011) (following *Riegel* and dismissing plaintiff's product liability claims regarding silicone gel-filled breast implants as preempted).[14]

D. Plaintiff Minh Nguyen's Derivative Loss of Consortium Claim Fails.

Because Plaintiff Rexina Mize's claims fail, her spouse's derivative loss of consortium claim (Count 5) fails. "One spouse cannot have a loss of consortium claim without a prior disabling injury to the other spouse." *Estate of Tucker ex rel. Tucker v. Interscope Records, Inc.*, 515 F.3d 1019, 1038–39 (9th Cir. 2008) ; *see also Jager v. Davol Inc.*, No. EDCV 16–1424 JGB (KKx), 2017 WL 696081, at *7 (C.D. Cal. Feb. 9, 2017) .

IV. CONCLUSION

Based on the above, Defendants respectfully request that the Court enter an order granting Defendants' Rule 12(b)(2) and Rule 12(b)(6) Motion to Dismiss and dismiss Plaintiffs' action, with prejudice, in its entirety.

[14] *See also Williams v. Allergan USA, Inc.*, No. CV–09–1160–PHX–GMS, 2009 WL 3294873, at *2–3 (D. Ariz. Oct. 14, 2009) (following *Riegel* and granting breast implant manufacturer's motion for summary judgment because plaintiff's product liability and negligence claims related to a ruptured silicone implant were preempted); *Dorsey v. Allergan, Inc.*, No. 3:08-0731, 2009 WL 703290, at *1–6 (M.D. Tenn. Mar. 11, 2009) (following *Riegel* and granting breast implant manufacturer's motion for summary judgment on preemption in case involving silicone gel breast implants); *Herbert v. Mentor*, No. 04–413 (MLC), 2007 WL 2893387, at *3–4 (D.N.J. Sept. 28, 2007) (granting Mentor's motion for summary judgment on preemption in case involving saline breast implants); *Cottengim v. Mentor Corp.*, No. 05–161–DLB, 2007 WL 2782885, at *2–5 (E.D. Ky. Sept. 24, 2007) (granting Mentor's motion for summary judgment on preemption in case involving saline breast implants); *Alfred v. Mentor Corp.*, No. 05–483–C, 2007 WL 708631, at *2–7 (W.D. Ky. Mar. 5, 2007) (granting Mentor's motion for summary judgment on preemption and other grounds in case involving saline breast implants); *Haddock v. Mentor Tex.*, No. Civ.A. 303CV2311B, 2005 WL 3542563, at *4 (N.D. Tex. Mar. 25, 2005) (granting Mentor's motion for summary judgment on preemption in case involving saline breast implants).

DATED: April 7, 2017

TUCKER ELLIS LLP

By: */s/Mollie F. Benedict*
Mollie F. Benedict
Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of April, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which shall send notification of such filing.

/s/ *Mollie F. Benedict*
Mollie F. Benedict